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Factors related to the detection of adulteration with pharmaceutical substances in food products claiming weight loss or sexual-performance enhancement

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ABSTRACT

This cross-sectional analytical study aimed to determine factors related to the detection of adulteration with pharmaceutical substances in food products that claimed to reduce weight or enhance sexual performance. Data were collected using a survey checklist and descriptive statistics, and multiple logistic regression was applied for data analysis. Pharmaceutical substances were detected in 36.7% of food products. According to multiple logistic regression analysis, the factors significantly correlated with the detection of weight reducing or sexual-performance enhancing pharmaceutical substances in food products were the absence or miscommunication of ingredient information and indication claiming statements. The indication claiming statements significantly correlated to adulteration with weight reducing compounds in food products. In addition, the absence or miscommunication of ingredient information and the expiration date was associated with the finding of sexual performance enhancing drugs. These results could benefit the concerned department as educational information for raising consumer awareness before deciding to buy food products.

Keywords: adulteration; dietary supplement; food product claims; sexual-performance enhancement; weight loss

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1. INTRODUCTION

From a socioeconomic viewpoint, the global food product market has grown continuously. These products are affordable and accessible, resulting in a higher consumption rate. Moreover, consumers have easy access to news and advertisement on food products through various media and can promptly purchase them to support their health conditions (Dickinson et al., 2014; Hys, 2020). These demands led to investments by several competitive entrepreneurs, who attempted to favor their customers differently. The strategies used to persuade the consumers to buy these products are varied and can sometimes be abusive by using overclaims in the media or adding prohibited pharmaceutical substances to products to boost the desired effects (Huang et al., 2017; Koncz et al., 2021; Vaale-Hallberg, 2012).

Currently, the problems regarding the adulteration of pharmaceutical substances in food products are a major concern worldwide. The adulteration causes harm to consumers' physical and mental health (Rocha et al., 2016). According to studies from the European Union, the United States, and Asia, the two food products that most commonly contain pharmaceutical ingredients were those claiming to reduce weight or enhance sexual performance (Ching et al., 2018; Czepielewska et al., 2018; Rocha et al., 2016). The compounds usually found to adulterate food products claiming weight reduction are appetite suppressants (sibutramine and its analog, fenfluramine, ephedrine, norephedrine, and phentermine), diuretics (hydrochlorothiazide, methyclothiazide chlorothiazide, furosemide, etc.), antidepressants (doxepin, fluoxetine, sertraline, and bupropion), and lipase inhibitor (orlistat). Conversely, phosphodiesterase-5 (PDE-5) enzyme inhibitors, e.g., sildenafil, tadalafil, vardenafil, and their analogs, have been detected in food products claiming to enhance sexual performance.

The compounds mentioned above constitute examples of adulterating substances in food products. However, other pharmaceutical ingredients in commercialized merchandise can also cause adverse effects and hypersensitivities among consumers (Eichner and Tygart, 2016; Ekar and Kreft, 2019). Hence, customers are at a higher risk of being affected by the unwanted substances in food. Although most countries have enacted consumer laws and regulations to protect consumers against food adulteration, the responsible organizations may not have monitored all available products. Therefore, we realized the importance of food product risk management, which would assist the evaluation of the chance that pharmaceutical substances are present in these products, especially those advertising weight loss and sexual enhancement. Our research aimed to determine the factors related to detecting pharmaceutical substances in food products claiming to reduce weight or enhance sexual performance.

2. MATERIALS AND METHODS

2.1 Study design and population

A cross-sectional analytical study was performed in 2019. Food products with drug substance quantification reports from the Thai Food and Drug Administration (Thai FDA) and Provincial Public Health Office between 2016 and 2018 were eligible for the study (636 items). The inclusion criteria for the analysis were as follows: food products claiming weight loss or sexual performance enhancement, and all text and pictures from the photographed labels of food products were present. Food products detected with adulteration unrelated to the label claims were excluded from the study. Therefore, 332 clearly photographed labels were included in the data analysis, of which 315 items were reported by the Thai FDA, whereas the Provincial Public Health Office reported the remaining 17 entries.

2.2 Data collection checklist

A data collection checklist was designed regarding the concerned factors/information. The checklist contained two parts.

Part 1: General details of the food product consisted of the food category, report of pharmaceutical substance adulteration, product name (Thai/English), and establishment's name and address. There was a total of five questions in this section.

Part 2: The information presented on the food product labels was classified into Thai Food Act information and indication claiming sections. The former included the food product registration number, ingredients, establishment's name and address, cautions, and expiration date. This section was presented as a checklist, indicating whether the information was present, absent or miscommunicated. There was a total of five questions in this first section. The latter referred to the indication claiming statements or images, which included the product name, pictures, texts, quality and safety standards certification of the product or manufacturing process, and trademarks. This section was provided as a checklist with three choices: not presented, presented without indication claiming, and presented with indication claiming. The latter section was composed of a total of five questions.

2.3 Validation of the data collection tool

2.3.1 Content validity

The content of the checklist was validated using the index of item-objective congruence (IOC) by three experts, including two regulators and one university professor, who determined if the content was relatable to the research objectives. Items with IOC scores less than 0.5 were revised. Items with IOC scores greater than 0.5, on the other hand, were reserved. They reported that 5 out of 15 questions needed revision, which had been revised for better clarity and objectivity.

2.3.2 Usability

The content validity qualified checklist was used to preliminarily collect the information of 10 marketed food products suspected of claiming the indication of weight reduction or sexual performance enhancement. The tool achieved suitability and collectability.

2.4 Data collection

The authors collected the characteristics of the food products following the checklist. This way, the presentation of texts, pictures, food categories, and manufacturer's information was compiled from the labels photographed from the food product collected for the drug substance analysis. The report on pharmaceutical ingredients was gathered from the Thai FDA food product analysis report provided by Thailand's Department of Medical Sciences and Medical Sciences Center. The food product registration number and the establishment's address were verified from the Thai FDA website.

2.5 Data analysis

Different presentations of the food product observed on the labels were described with descriptive statistics. Analytical statistics were used in logistic regression and the analysis of the relationship between the factors/information and the detection of pharmaceutical substance adulterations. Factors related to the detection of adulteration from the univariate analysis were chosen for multiple logistic regression analysis. The factors were considered in the logistic regression using the enter mode, and the odds ratio (OR), adjusted odds ratio, and 95% confidence interval were presented.

3. RESULTS

3.1 General information on the food products

Among the inspected food products, 74.4% were considered products for weight reduction and were categorized as weight reducing food products. The remaining 24.7% pertained to the sexual-performance enhancement and were categorized as sexual-performance enhancing food products. In addition, 0.9% were analyzed for weight reducing and sexual-performance enhancing substances and classified into both categories. Most of the food products inspected were food supplements (69.9%).

The information provided on the food product labels was classified into two groups: those following the Thai Food Act on labeling and indication claiming. According to the Food Act, companies must provide the food product registration number, ingredients, establishment's name and address, cautions, and expiration date. Most labels complied with the presentation of ingredients (73.7%), establishment details (79.2%), cautions (66.4%), and expiration date (67.3%). However, the findings revealed that half of the food products presented false registration numbers (52.7%). Almost half of the presented product name was unrelated to the registered name (45.1%).

The indication claiming information section consisted of product names, pictures, indication statements, pictures/symbols/texts referring to certified standards on quality and safety of the manufacturing, and trademarks. The results indicated that there was mostly no indication claiming in the product names (80%), no indication claiming statement on the labels (71%), and no indication signifying trademark (84%). In contrast, the labels contained pictures representing the indication (59.1%) and pictures/symbols/texts referring to certified standards (72.2%), as presented in Table 1.

Indication claiming statements were found on almost one-third of the labels, classified into two indications. Firstly, 22.9% of the labels contained statements claiming weight reduction. The statements were 'weight loss', 'reduce cholesterols', 'lipid reducing', 'providing good shape' (S-curved body, fit, firm, slim), 'reduce appetite', 'rapid satiety', 'cellulite diminishing', 'change you from XL to S', 'burn block break', 'clear' (of fat or lipid), 'high thermogenic effect', 'intake 2–4 sachets daily for weight-reducing effectiveness', etc. Secondly, information indicating the enhancement of sexual performance was found on 6% of the labels. The statements were 'returning happiness to the man', 'solution to erectile dysfunction, 'treatment of impotence', 'enhancing sexual performance, 'dietary supplement for men', 'take two capsules 15–30 minutes before the intercourse', etc.

Pictures or graphics representing the indications were also presented on the labels, classified into three categories. First, 37.7% of the labels showed pictures implying weight reduction, including images or graphics of a woman with a good shape, containers or packaging with a constricted waist-like shape, images of a woman with a waist tape measure or tape measure alone, weighing machine graphics, pictures of a certain body part, images of before and after product consumption, etc. Moreover, pictures that signified the enhancement of sexual performance were on 7.9% of the items, including images or graphics of a man with a good body type, images of animals that relate to strength (such as horses, dragons, or bulls), male symbol, tuxedos, etc. Lastly, pictures of public figures were also presented on the product labels, for example, celebrities, performers, singers, and teen idols.

Regarding the texts, images, or logos representing the manufacturing process's quality and safety standard certifications, this information appeared on 66.56% of the label. Examples included a Good Manufacturing Practice (GMP) logo, texts indicating GMP approval, logo or text referring to the International Organization for Standardization (ISO) approval, logo or text implying the approval of the Hazard Analysis Critical Control Point (HACCP), etc. Moreover, information leading to the understanding of the approved quality and safety standard or guarantee of the food products was visible (24.7%). This information included 'assuring kg lost', '100% effective within a box/blister pack', 'result guaranteed in days', 'surely slimmer', 'weight loss confirmed', 'safe', 'not dangerous', 'no side effects', 'no CNS depressing effect', 'no rebound effect', 'fat eliminating formula', 'anti-drug resistant formula', '100% natural extract' or other symbols, logos or texts suggesting the approval of international agencies and the Thai FDA, etc.

3.2 Detection of adulteration with pharmaceutical substances

Pharmaceutical substances were adulterated in 36.4% of the food products. Weight reducing active compounds, such as bisacodyl, deoxy-D2PM (2-diphenylmethylpyrrolidine), fluoxetine, orlistat, phenolphthalein, and sibutramine were found (20%). Moreover, 16.4% of the inspected items carried sexual-performance enhancing drugs (sildenafil or tadalafil).

3.3 Presentation of text on the product labels concerning the adulteration

Considering the information required by the Food Act in all products, the products with the absence or miscommunicated ingredient information, establishment's name and address, and cautions were more likely to be adulterated with pharmaceutical substances than those with correct information. In products claiming to enhance sexual performance, in particular, the absence and incorrect presentation of all necessary information were related to the finding of drug substance augmentation (Figure 1).

Among all products, those with an indication claiming in the product name and indication claiming statement or picture on the labels exhibited a higher incidence of adulteration than those with no indication claim (Figure 2).

Table 1. Percentage of food products classified by food category and label presentation

Characteristics	Numbers of food products (percentage)		
	Products claimed to reduce weight	Products claimed to enhance sexual performance	Total
Food product category	**(n=250)**	**(n=85)**	**(n=335)**
Food supplement	168 (67.2)	66 (77.6)	234 (69.9)
Coffee	75 (30.0)	19 (22.4)	94 (28.1)
Drinks	5 (2.0)	-	5 (1.5)
Tea	2 (0.8)	-	2 (0.6)
Regulation information			
Registration number	**(n=250)**	**(n=84)**	**(n=334)**
Correctly presented	117 (46.8)	36 (42.9)	153 (45.8)
Absent	3 (1.2)	2 (2.4)	5 (1.5)
Misused	130 (52.0)	46 (54.8)	176 (52.7)
Ingredients	**(n=250)**	**(n=85)**	**(n=335)**
Correctly presented	196 (78.4)	51 (60.0)	247 (73.7)
Absent	1 (0.4)	1 (1.2)	2 (0.6)
Misused	53 (21.2)	33 (38.8)	86 (25.7)
Establishment's name and address	**(n=244)**	**(n=83)**	**(n=327)**
Correctly presented	193 (79.1)	66 (79.5)	259 (79.2)
Absent	25 (10.2)	8 (9.6)	33 (10.1)
Misused	26 (10.7)	9 (10.8)	35 (10.7)
Cautions	**(n=166)**	**(n=66)**	**(n=232)**
Correctly presented	111 (66.9)	43 (65.2)	154 (66.4)
Absent	6 (3.6)	1 (1.5)	7 (3.0)
Misused	49 (29.5)	22 (33.3)	71 (30.6)
Expiration date	**(n=246)**	**(n=84)**	**(n=330)**
Correctly presented	170 (69.1)	52 (61.9)	222 (67.3)
Absent	1 (0.4)	-	1 (0.3)
Misused	75 (30.5)	32 (38.1)	107 (32.4)
Indication claiming information			
Product name	**(n=250)**	**(n=85)**	**(n=335)**
No indication claiming	198 (79.2)	70 (82.4)	268 (80.0)
Claiming weight reduction	52 (20.8)	-	52 (15.5)
Claiming sexual performance enhancement	-	15 (17.6)	15 (4.5)
Pictures	**(n=250)**	**(n=85)**	**(n=335)**
No indication claiming	95 (38.0)	42 (49.4)	137 (40.9)
Claiming weight reduction	118 (47.2)	-	118 (35.2)
Claiming sexual performance enhancement		40 (47.1)	40 (11.9)
Claiming weight reduction and sexual performance enhancement	31 (12.4)	1 (1.2)	32 (9.6)
No indication claiming	-	1 (1.2)	1 (0.3)
Claiming weight reduction with pictures of public figures	6 (2.4)	-	6 (1.8)
Claiming sexual performance enhancement with pictures of public figures	-	1 (1.2)	1 (0.3)
Texts	**(n=250)**	**(n=85)**	**(n=335)**
No indication claiming	174 (69.6)	64 (75.3)	238 (71.0)
Claiming weight reduction	75 (30.0)	-	75 (22.4)
Claiming sexual performance enhancement	-	20 (23.5)	20 (6.0)
Claiming weight reduction and sexual performance enhancement	1 (0.4)	1 (1.2)	2 (0.6)
Quality and safety standards certification of the product or manufacturing process	**(n=250)**	**(n=85)**	**(n=335)**
Text or picture presented	59 (23.6)	34 (40.0)	93 (27.8)
Text or picture not presented	191 (76.4)	51 (60.0)	242 (72.2)
Trademarks	**(n=113)**	**(n=18)**	**(n=131)**
No indication claiming	94 (83.2)	16 (88.9)	110 (84.0)
Claiming weight reduction	19 (16.8)	-	19 (14.5)
Claiming sexual performance enhancement	-	2 (11.1)	2 (1.5)

Figure 1. Percentage of the presented information that followed the regulation on the labels of food products being adulterated with pharmaceutical substances

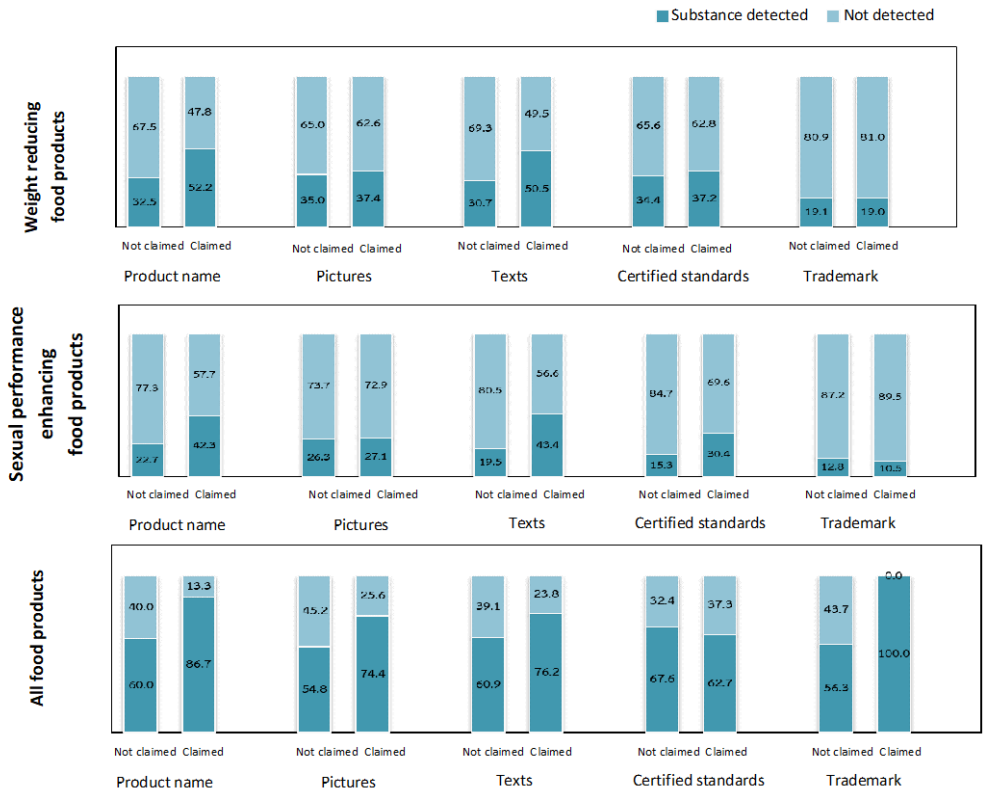

Figure 2. Percentage of the indication claiming information presented on the labels of pharmaceutical substance adulterated food products

3.4 Identification of factors related to the detection of drug adulteration in food products

The results revealed that several label characteristics were significantly related to the detection of drugs for weight reduction or sexual-performance enhancement in food products were product name that signified the indication, the absence or incorrect presentation of the ingredients, establishment's name and address, cautions, expiration date and indication claiming statements. Specifically, the factors that significantly correlated with the detection of weight reducing substances were the product name, the absence or incorrect presentation of the establishment's name and address, cautions, indication claiming statements, and texts or pictures referring to quality and safety standard certification. Lastly, the absence or incorrect presentation of the ingredients and expiration date significantly correlated with the finding of sexual-performance enhancing substances in the food products.

3.5 Factors related to the detection of weight reducing or sexual-performance enhancing drugs in food products

The label's information related to detecting weight reducing or sexual-performance enhancing active compounds included the absence or misuse of ingredient information and the presentation of indication claiming statements. More specifically, the information that exhibited a significant relationship with the discovery of weight reduction substances was the indication claiming statements. Moreover, the absence or miscommunication of ingredient presentation and the expiration date significantly correlated with detecting sexual performance-enhancing drugs (Table 2).

4. DISCUSSION

Among the food products included in this study, 36.4% were adulterated with pharmaceutical substances. More precisely, 26.8% were contaminated with weight reducing substances, whereas 64.7% carried sexual-performance enhancing active compounds. These findings indicated that more than 50% of the food products that claimed sexual-performance enhancement were adulterated with a drug. The number of products in which sexual-performance enhancing drug adulteration was detected concord with a study in Malaysia (Bujang et al., 2017). The study found that 54.8% of herbal and food products were adulterated with at least one phosphodiesterase-5 (PDE-5) inhibitor or analog. However, this amount differed from that reported by a study performed in Korea that screened foods and dietary supplements advertised as providing sexual enhancement (Lee et al., 2019). The study has reported that 30.4% of the samples were adulterated.

According to the multiple logistic regression analysis, considering the information relating to detecting adulteration with weight reducing or sexual-performance enhancing substances, three factors were significantly correlated with adulteration, including the absence or miscommunication of the ingredient and expiration date information, together with the presence of indication claiming statements. According to the Thai Food Act (Food Act, 1979), the information on the products' ingredient list was miscommunicated in various ways, such as the order of the ingredients (not listed from the highest to the lowest content), the absence or incorrect presentation of a unit of measurement for each ingredient, lack of presentation of the ingredients in the local language (Thai), and absence of information on each ingredient content. This reflected that entrepreneurs, who complied with the food product labeling regulations, were less likely to launch products with drug adulteration.

The absence or miscommunication of the expiration date on the label significantly correlated to the detection of sexual-performance enhancing drug smuggling. We detected 38.1% of sexual-performance enhancing products with expiration date presentation that did not comply with the regulations. The miscommunication of the date presentations included not stating the term 'expired' or 'best before' in the local language (Thai), not presenting the date order as regulated, and not presenting the month in the local language (Thai). Although the expiration date was shown on all food products in this category, its incorrect presentation in terms of numbers, language, or symbols may have led to consumers misunderstanding the exact expiration date. In concordance with the ingredient presentation, the non-adulterated food products were more likely to appropriately present the expiration date than the drug-adulterated goods.

Furthermore, the indication claiming statements were also significantly correlated with the detection of drug substances in food products, when considering all products and products that claimed to reduce weight. This finding agrees with studies in several countries, which reported that food products with statements alluding to weight reduction exhibited adulteration (Ahmed et al., 2019; Campbell et al., 2013; Dastjerdi et al., 2018; Hachem et al., 2016).

These claims affected the consumers' decisions regarding the purchase of products, thus forcing the establishments and entrepreneurs to state the claims on the label. However, this was illegal from both labeling and advertising viewpoints. The companies were careless of law, as the penalty of labeling misuse crime in Thailand is 30,000 THB (approx. 1,000 USD), whereas a fine of only 5,000 THB (approx. 170 USD) is specified for illegal indication claiming (Food Act, 1979); both penalties are considered very low, compared with companies' profit.

The absence or miscommunication of the ingredient information, the expiration date, and the presence of indication claiming statements significantly correlated with drug detection in food products. These factors can only be pooled to predict the adulteration of all food merchandise in just 14.4% of cases (Nagelkerke R^2, 0.144). Moreover, only 16.5% of the cases were predictable (Nagelkerke R^2, 0.165) when considering weight reducing products, and 17.5% when considering sexual-performance enhancing food products (Nagelkerke R^2, 0.175). Regarding the sexual performance-enhancing drugs, our results suggested that there may be other factors affecting adulteration with drug substances that were not mentioned in this study, such as advertisement types, selling location (such as drug stores, kiosks, online shopping, and direct selling), etc. Other considerable factors, such as product price, previous adulteration report, and manufacturing or importing site, could be further included in a study encompassing a more significant number of food products.

Table 2. Factors related to the detection of weight reduction or sexual-performance enhancement drugs adulterated in food products from multiple logistic regression analysis

Factors	Adjusted odds ratio	95% confidence interval	p-value
All products			
Food Product name			
Not claimed	1.00		
Claimed	1.88	0.89-3.93	0.10
Ingredients			
Correctly presented	1.00		
Absent or misused	2.33	1.20-4.51	0.01*
Establishment's name and address			
Correctly presented	1.00		
Absent or misused	1.18	0.58-2.38	0.64
Indication claiming statements			
Not shown	1.00		
Presented	2.06	1.08-3.95	0.03*
Cautions			
Correctly presented	1.00		
Absent or misused	1.39	0.74-2.62	0.30
Expiration date			
Correctly presented	1.00		
Absent or misused	1.11	0.60-2.03	0.74
Cox & Snell R^2 = 0.107; Nagelkerke R^2 = 0.144; Percentage correct = 64.3			
Weight-reducing food products			
Food Product name			
Not claimed	1.00		
Claimed	2.18	0.91-5.25	0.08
Establishment's name and address			
Correctly presented	1.00		
Absent or misused	1.48	0.64-3.40	0.36
Indication claiming statements			
Not shown	1.00		
Presented	3.05	1.44-6.45	<0.01*
Cautions			
Correctly presented	1.00		
Absent or misused	1.43	0.67-3.07	0.36
Texts or pictures of quality and safety standard certification			
Not shown	1.00		
Presented	0.92	0.36-2.34	0.86
Cox & Snell R^2 = 0.121; Nagelkerke R^2 = 0.165; Percentage correct = 70.1			
Sexual-performance-enhancing food products			
Ingredients			
Correctly presented	1.00		
Absent or misused	2.97	1.06-8.34	0.04*
Expiration date			
Correctly presented	1.00		
Absent or misused	3.38	1.16-9.84	0.03*
Cox & Snell R^2 = 0.127; Nagelkerke R^2 = 0.175; Percentage correct = 69.0			

Note: * = statistical significance.

5. CONCLUSION

In this study, the factors related to the detection of adulteration with pharmaceutical substances in food products claiming weight loss or sexual-performance enhancement were investigated. It was found that more than one-third of the food products were adulterated with pharmaceutical substances. Several label characteristics were significantly related to the detection of drugs for weight reduction or sexual-performance enhancement. Importantly, the absence or miscommunication of ingredient information, expiration date, and indication claiming statements were related to the detection of weight reducing or sexual-performance enhancing pharmaceutical substances in food products. The indication claiming statements had the highest impact on weight reduction substances detection in food product. Thus, the absence or miscommunication of ingredient presentation and the expiration date were major concerns for the detection of sexual-performance enhancing drugs. These findings

could be helpful to the FDA and concerned organizations for developing public educational media on product label assessment, product registration verification, and characteristics of the product labels that are likely to be adulterated with unwanted substances. Finally, the findings may be beneficial to the concerned organizations as knowledge and decision-making information could be provided to the consumers for further safety while purchasing food products.

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